

AGENDA
CIRCULATORY SYSTEM DEVICES PANEL

March 4, 2002

Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD

10:00 – 4:00	PMA Supplement Discussion, Recommendations, and Voting	
10:00 a.m.	Call to Order	Warren Laskey, M.D., Acting Chairperson
10:05 – 10:15 a.m.*	Open Public Hearing*	
10:15 – 11:15 a.m.	Sponsor Presentation: Thoratec Corporation P910014/S016, HeartMate VE LVAS Donald A. Middlebrook, Vice President Regulatory Affairs and Quality Assurance Victor Poirier, Chief Technology Advisor Eric Rose, MD, REMATCH Principal Investigator, Chairman Department of Surgery Columbia-Presbyterian Medical Center, NY Lynne W. Stevenson MD, REMATCH Medical Management Committee Chair & Director Cardiomyopathy and Heart Failure Brigham & Woman's Hospital, Boston	
11:15 – 12:00 p.m.	FDA Presentation Michael Berman, PhD, lead reviewer Julie Swain, MD, clinical reviewer Gerry Gray, PhD, statistical reviewer	
12:00 p.m.	Adjourn – Break for Lunch	
1:00 p.m.	Call to Order : Open Discussion	Warren Laskey, M.D.
2:15 – 2:30 p.m.	Break	
2:30 – 3:45 p.m.	Open Panel Discussion, Recommendations and Voting	Warren Laskey, M.D.
3:45 – 4:00 p.m.	Open Public Hearing*	
4:00	Adjourn	
4:15 – 5:00 p.m.	Closed session***	

OPEN PUBLIC HEARINGS*

Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee.

Dr. Ewing will present the speakers who have requested time for presentation to the Panel. After the scheduled speakers have spoken, the Chair may ask them to remain if the committee wishes to question them further. Dr. Laskey will recognize unscheduled speakers as time allows.

Note: Only the Chair and members of the Panel may question speakers during the open public hearing.

CLOSED SESSION***

The session will be closed to the public from 4:15-5:00p.m., in order to allow the Panel to hear trade secret and/or confidential information.